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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,561	12/12/2003	David James Dooley	PC 25627A	3925

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
GROTON, CT 06340

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
04/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/735,561	DOOLEY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7, 9 and 11-12 are presented for examination.

Applicant's Amendment filed January 18, 2008 has been received and entered into the present application.

Claims 7, 9 and 11-12 remain pending and under examination.

Applicant's arguments, filed January 18, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 9 and 11-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bryans et al. (WO 99/21824; 1999) in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th

Edition, p.481-482), each already of record, for the reasons of record set forth at pages 2-6 of the previous Office Action dated July 18, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the present rejection by alleging that, while it may be true that pain is a symptom of fibromyalgia, *Merck* fails to raise the reasonable expectation that treating a symptom (one of potentially many symptoms) of fibromyalgia would necessarily ameliorate the overall condition of fibromyalgia. Applicant asserts that the Office has failed to give any reason why this would be the case and further alleges that "treatment of the syndrome-fibromyalgia-therefore cannot be expected to occur merely be addressing one of the many symptoms or associated syndromes" because an agent useful for ameliorating pain would not address other symptoms of the condition, such as unrefreshing sleep, disturbed mood, or fatigue (p.4, Remarks). Still further, Applicant relies upon the fact that *Merck* discloses that pain medication (such as aspirin or other NSAIDS) have not generally been shown to be effective in treating fibromyalgia such that there is no suggestion in this reference that an agent known to be useful in treating pain would be further useful for treating fibromyalgia. Applicant additionally states that claims 9 and 11-12 are directed to the treatment of fibromyalgia and a concomitant disorder and alleges that the references fail to describe or even suggest the treatment of fibromyalgia and a concomitant disorder as claimed.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant asserts that the treatment of a symptom, arguably even a *major* symptom, of fibromyalgia (in this case, pain) would not necessarily ameliorate the condition as a whole. However, the basis of Applicant's traversal is unclear in the absence of any specific reasons to support the allegation that the amelioration of a symptom of fibromyalgia would not treat and/or ameliorate the condition as a whole. Applicant has solely claimed the "treatment of fibromyalgia", not the comprehensive treatment, or in an extreme sense, cure, of the entire syndrome (and *all* of its related symptoms) itself. An ordinary and customary use of the term "treatment" is reasonably understood to mean any amelioration or

improvement of such a disease or disorder and/or the symptoms or conditions that directly result from and, therefore, characterize, the same disease or disorder. Accordingly, any improvement in the pain that is associated with fibromyalgia by inducing an analgesic effect necessarily treats, i.e., improves or ameliorates the condition of fibromyalgia as a whole.

Even if, *arguendo*, Applicant had provided specific reasons to support this allegation, such a conclusion is disputed in light of standard medical practice. It is well accepted in the medical and pharmaceutical arts that the treatment of a known symptom, particularly a major symptom, of an overall condition using a therapy effective for treating such a symptom would necessarily ameliorate the overall condition as a whole.

For example, fentanyl is commonly used in cancer patients to ameliorate debilitating pain associated with the condition. While fentanyl itself may not actually cause tumor regression and remission, the fact that the fentanyl is ameliorating the pain resulting from the overall condition of cancer necessarily ameliorates the cancer syndrome by eliminating a symptom (again, in this example, pain) of the overall condition. Such a situation is analogous to the present case. Bryans et al. teaches that the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is effective to treat, *inter alia*, pain, which, as evidenced by *Merck*, is a symptom of fibromyalgia. In view of such teachings, the cited prior art provides (1) a clear suggestion and/or motivation to employ such a compound in a subset of patients experiencing pain as it results from the overall condition of fibromyalgia to exploit its analgesic effect(s) and (2) the very treatment of a known symptom of the overall condition of fibromyalgia would necessarily ameliorate (i.e., improve) the comfort of a fibromyalgia patient by eliminating (or, at the very least, reducing) a symptom of the overall condition. The fact that the disclosed compound may not ameliorate each and every symptom of fibromyalgia (since Applicant appears to be presently alleging that, unless the compound is effective to treat *all* of the symptoms of fibromyalgia, it would not be at all useful for the treatment of fibromyalgia *per se*) is immaterial to the fact that it would, as evidenced by

Bryans et al., be effective to treat *pain*, which is a symptom of the condition and, therefore, would be reasonably expected to improve the overall medical condition of a fibromyalgia patient.

In addition, contrary to Applicant's assertions, the cited references, in fact, do provide a reasonable expectation of success in treating fibromyalgia. Bryans et al. teaches that the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is effective to treat, *inter alia*, pain, i.e., 100% of all patients experiencing pain, without exclusion. Of this entire population of patients experiencing pain, *Merck* provides the factual extrinsic evidence demonstrating that a subpopulation of patients experiencing pain also suffers concomitantly from fibromyalgia. Accordingly, the suggestion of Bryans et al. to use the claimed (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid for treating any patient experiencing pain, such as those patients also suffering from fibromyalgia, provides at least a reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of fibromyalgia patients as would be expected in the treatment of patients experiencing pain *per se*, absent factual evidence to the contrary.

Further, Applicant again relies upon the fact that *Merck* teaches the less than optimal pain management efficacy of aspirin and other NSAIDs in treating fibromyalgia pain to assert that the (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid compound would also not have efficacy in treating fibromyalgia pain. However, Applicant has extrapolated the efficacy from a specific genus of analgesics (i.e., aspirin and NSAIDs) to a specific species of medication (i.e., the compound of Bryans et al.) without providing any reasoning or evidence to support such a conclusion as to why one of ordinary skill in the art at the time of the invention would have expected similar efficacy using the compound taught by Bryans et al. Generic allegations that aspirin or other NSAIDs are not particularly effective for ameliorating fibromyalgia pain fail to establish any basis for extrapolating such a conclusion to the claimed compound [i.e., that taught by Bryans et al.; (3S,4S)-(l-aminomethyl-3,4-dimethyl-cyclopentyl)- acetic acid], since aspirin and NSAIDs have a distinctly different mechanism of action than the claimed compound. In fact,

this different mechanism of action alone would have supported the conclusion that the two compounds would have been reasonably expected to differ in activity such that the efficacy seen with one type of analgesic would not necessarily have been suggestive of the same, or even substantially similar, efficacy with a completely different type of analgesic in the absence of any reasoning or evidence upon which to rely. Accordingly, Applicant's arguments that *Merck* teaches away from the use of an analgesic for fibromyalgia based upon the less than optimal efficacy of aspirin and other NSAIDs for the same purpose are clearly not persuasive.

Moreover, Applicant's allegation that the cited prior art also fails to teach the treatment of fibromyalgia and a concomitant disorder, such as, *inter alia*, anxiety, irritable bowel syndrome, etc., is also unpersuasive. Bryans et al. teaches that the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is effective to treat, *inter alia*, pain, anxiety, and irritable bowel syndrome, which, as evidenced by *Merck*, are each symptoms of fibromyalgia. In view of such teachings, the cited prior art provides (1) a clear suggestion and/or motivation to employ such a compound in a subset of patients experiencing pain, anxiety and irritable bowel syndrome (IBS) as they each result from the overall condition of fibromyalgia to exploit its analgesic, anxiolytic and IBS-ameliorating effect(s) and (2) the very treatment of known symptoms of the overall condition of fibromyalgia would necessarily ameliorate (i.e., improve) the comfort of a fibromyalgia patient by eliminating (or, at the very least, reducing) various symptoms of the overall condition. The fact that the disclosed compound may not ameliorate each and every symptom of fibromyalgia (since Applicant appears to be presently alleging that, unless the compound is effective to treat *all* of the symptoms of fibromyalgia, it would not be at all useful for the treatment of the overall syndrome of fibromyalgia) is immaterial to the fact that it would, as evidenced by Bryans et al., be effective to treat *pain, anxiety and IBS*, which are each symptoms of the condition and, therefore, would improve the overall medical condition of a fibromyalgia patient.

As above, the cited references do provide a reasonable expectation of success in treating

fibromyalgia and a concomitant disorder (e.g., anxiety, IBS, etc.). Bryans et al. teaches that the compound (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid is effective to treat, *inter alia*, pain, i.e., 100% of all patients experiencing pain, as well as anxiety, and irritable bowel syndrome (i.e., 100% of all patients experiencing anxiety and 100% of all patients experiencing IBS) without exclusion. Of this entire population of patients experiencing pain, anxiety and IBS, *Merck* provides the factual extrinsic evidence demonstrating that a subpopulation of patients experiencing pain, anxiety and IBS also suffers concomitantly from fibromyalgia. Accordingly, the suggestion of Bryans et al. to use the claimed (3S,4S)-(1-aminomethyl-3,4-dimethyl-cyclopentyl)-acetic acid for treating any patient experiencing pain, anxiety and IBS, such as those patients also suffering from fibromyalgia, provides at least a reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of fibromyalgia patients as would be expected in the treatment of patients experiencing pain, anxiety or IBS *per se*, absent factual evidence to the contrary.

For these reasons, and those previously made of record at pages 2-6 of the previous Office Action dated July 18, 2007, rejection of claims 7, 9 and 11-12 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 9 and 11-12 remain provisionally rejected on the grounds of nonstatutory obviousness-

type double patenting as being unpatentable over claim 16 of copending U.S. Patent Application No. 10/935,824; or claim 2 of copending U.S. Patent Application No. 11/675,389; each alternatively in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, p.481-482), each already of record, for the reasons of record set forth at pages 6-8 of the previous Office Action dated July 8, 2007, of which said reasons are herein incorporated by reference.

Claims 7, 9 and 11-12 remain provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending U.S. Patent Application No. 11/688,001 in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, p.481-482), each already of record, for the reasons of record set forth at pages 8-9 of the previous Office Action dated July 8, 2007, of which said reasons are herein incorporated by reference.

Claims 7, 9 and 11-12 remain rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,635,673 (2003) in view of Beers et al. (*The Merck Manual of Diagnosis and Therapy*, 17th Edition, p.481-482), each already of record, for the reasons of record set forth at pages 9-10 of the previous Office Action dated July 8, 2007, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejections, stating that the rejections are improper. Applicant asserts that the purpose of a rejection under the doctrine of obviousness-type double patenting is to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent when one or more claims in the subject patent application are not patentably distinct from the subject matter claimed in a commonly owned patent. Still further, Applicant alleges that the specification of the commonly owned patent or patent application may only be considered in certain circumstances "but it is improper to combine the teachings of the commonly owned patent or patent application with another

reference, as has been done here." (p.5, Remarks)

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant alleges that the rejections are improper, but fails to advance any substantive reasons to support this allegation. In the absence of specific reasons and/or explanation provided by Applicant as to why it is believed that the instant rejections are improper, the Examiner relies completely upon the reasons provided in the previous Office Action dated July 8, 2007 at pages 6-10 as to why one or more claims in the instant case are not patentably distinct from the subject matter claimed in the cited copending and/or patented applications. Such reasons are herein incorporated by reference and are not repeated herein so as not to burden the record.

Furthermore, in response to Applicant's allegation that the instant rejections improperly relied upon the teachings provided in the copending and/or patented specification, Applicant is reminded that the specification of the copending and/or patented applications was cited *solely* to provide a definition for a term used in one or more of the copending and/or patented claims. Contrary to Applicant's assertions, citation of the specification in this manner is proper in accordance with the MPEP at §804(II)(B)(1), which states, "The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.,* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)...Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent."

In the absence of any additional remarks to the contrary, the rejections remain proper for the reasons provided *supra* and those previously set forth at pages 6-10 of the Office Action dated July 8, 2007 and are properly **maintained**.

Conclusion

Rejection of claims 7, 9 and 11-12 remains proper and is **maintained**.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

April 2, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614